



POCKET NO.: ALZA-0141

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**In Re Application of:**

**George Guittard, et al.**

**Confirmation No.: 4150**

**Application No.: 09/785,805**

**Group Art Unit: 1616**

**Filing Date: February 16, 2001**

**Examiner: Konata M. George**

**For: METHOD FOR THE MANAGEMENT OF INCONTINENCE**

**EXPRESS MAIL LABEL NO: EV 160092090 US**  
**DATE OF DEPOSIT: January 5, 2004**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

- ☒ In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in § 1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or

before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

- ☐ In accordance with § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Certification in Accordance with § 1.97(e) is attached; or

☐ The fee of **\$180.00** as set forth in § 1.17(p) is attached.

- ☐ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:

☐ Certification in Accordance with § 1.97(e) is attached;  
or

☐ The fee of **\$180.00** as set forth in § 1.17(p) is attached.

- ☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of **\$180.00** as set forth in § 1.17(p).

- ☒ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

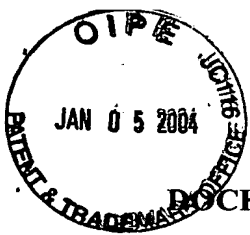
- ☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith

- ☐ Copies of references listed on the attached Form PTO 1449 are not required to be submitted pursuant to the June 30, 2003 recent revisions to 37 CFR § 1.98(a)(2)(i).

## EXCEPT THAT:

- ☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☐ In accordance with § 1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application:
- ☐ Copies of references [list as appropriate] listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior Application No. \_\_\_\_\_, filed \_\_\_\_\_.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.



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- ☐ The relevance of those listed references which are not in the English language is as follows:
- ☒ There are no listed references which are not in the English language.

Date: *January 5, 2004*

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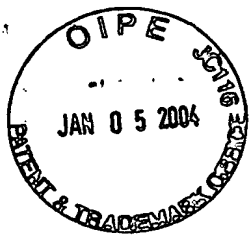
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<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office		Docket No. ALZA-0141	Application No. 09/785,805
		Applicant George Guittard, et al.	
		Filing Date February 16, 2001	Group 1616
		Confirmation No. 4150	
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	52	Abdou, H.M., "Dissolution," Remington's Pharmaceutical Sciences, 17 <sup>th</sup> Ed., 1985, Chapter 35, 653-666	
	53	Andérberg, E.K., et al., "Physicochemical aspects of drug release – X. Investigation of the applicability of the cube root law for characterization of the dissolution rate of fine particulate materials," <i>International Journal of Pharmaceutics</i> , 1990, 62, 143-151	
	54	Enomoto, et al., "Sustained release formulations containing oxybutynin chloride," <i>Chemical Abstracts</i> , April 4, 1994, 120(14), 173491	
	55	Enomoto, et al., "Sustained release preparation of oxybutynin chloride," <i>Chemical Abstracts</i> , May 2, 1994, 120(18), 227011	
	56	Grafton, P., "General principles for designing with plastics," <i>Modern Plastics Encyclopedia</i> , October 1969, 46(10A), 62-70	
	57	Nisson, C.G., et al., "Comparison of a 10-mg controlled release oxybutynin tablet with a 5-mg oxybutynin tablet in incontinent patients," <i>Neurology &amp; Urodynamics</i> , 1997, XP002099745, 16, 533-542	
	58	The United States Pharmacopeia/The National Formulary, "Dissolution," <i>USP XXII, NF XVII</i> , January 1, 1990, 711,1578-1579	
	59	The United States Pharmacopeia/The National Formulary, "Dissolution," <i>USP 23/NF18</i> , January 1, 1995, 711, 1791-1796	
	60	The United States Pharmacopeia/The National Formulary, "Test solutions," <i>UPS 23/NF180</i> , January 1, 1995, 2052-2053	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	

U. S. PATENT DOCUMENTS

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	Applicant George Guittard, et al.	
	Filing Date February 16, 2001	Group 1616
	Confirmation No. 4150	

**FOREIGN PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Country	Translation	
					YES	NO
	67	WO 96/12477	05/0296	PCT		
	68	WO 96/37202	11/28/96	PCT		
	69	5 33951	12/21/93	Japan		
	70	6 9388	01/18/94	Japan		
<b>EXAMINER</b>				<b>DATE CONSIDERED</b>		